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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
CHERNYSHEV, OLGA N	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/547,843
Filing Date: September 06, 2005
Appellant(s): HORIGUCHI ET AL.

William J. Simmons
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 04, 2009 appealing from the Office action mailed December 10, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1, 2, 4-7 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility.

The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The specification fails to disclose a specific biological function, relevance to a pathological condition, or any other basis for patentable utility, of the instant claimed molecules to a person skilled in the art at the time the application was filed. Therefore, the requirements of the 35 U.S.C. 101, utility, have not been met.

There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this

utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. Specifically, the present invention relates to "a prophylactic/therapeutic agent for a neurodegenerative disease, [and] a β-amyloid production inhibitor" (p. 1 of the specification), and is based on the hypothesis that "a target gene for creating a medicine for neurodegenerative diseases can be found in genes participating in endoplasmic reticulum stress response" (p. 2 of the specification). The instant specification explains that the claimed polynucleotide of SEQ ID NO: 2 and encoding protein, designated C1 protein, of SEQ ID NO: 1 (p. 64 of the instant specification) were identified by "exhaustive analysis of gene expression in nerve cells against endoplasmic reticulum stress" (top at p. 2). The specification further asserts that "[t]he protein of the present invention regulates repair and decomposition of abnormal proteins, neuronal death, amyloid production, etc. because its expression is increased upon application of endoplasmic reticulum stress to nerve cells" (p. 30). The examples using rat primary nerve cells show changes in C1 gene expression in response to different experimental conditions, pp. 65-67.

Specifically, Example 4, p. 69 of the instant specification demonstrates that cells transfected with C1 gene had slightly increased survival rate as compared to control cells (see Figures 1 and 2). Example 5, p. 69, describes results of experiments, in which two groups of cells

- transformed with C1 gene and transformed with GFP gene - were examined for spontaneous Aβ secretion in culture. It is stated that the cells transfected with C1 gene secreted less Aβ than the cells transfected with GFP. The specification fails to explain relevance of these experiments to support the asserted clinical application of the claimed C1 protein of SEQ ID NO: 1 and its encoding DNA.

The specification asserts the utility of the claimed molecules at p. 30, for example – "the protein of the present invention and the DNA of the present invention can be used as safe pharmaceuticals such as prophylactic/therapeutic agents for diseases such as neurodegenerative diseases (for example, Alzheimer's disease [e.g., familial Alzheimer's disease, juvenile Alzheimer's disease, sporadic Alzheimer's disease, mild cognitive impairment etc.], cerebral amyloid angiopathy, Parkinson's disease, Down's syndrome, amyotrophic lateral sclerosis, prion disease, Creutzfeldt-Jakob disease, Huntington's disease, diabetic neuropathy, multiple sclerosis etc.). The protein of the present invention and the DNA of the present invention can also be used as a β-amyloid production inhibitor etc.". However, the record does not support the asserted utility as stated. The specification fails to explain how spontaneous secretion of Aβ in cells transfected with C1 relates to etiology of Alzheimer's disease in particular and to neurodegenerative diseases in general. According to the knowledge in the art, neurodegenerative diseases do not have common etiology related to processing of amyloid (Aβ). Moreover, the experiments on cells with artificially altered genotype (overexpression of C1 gene) do not represent an art-accepted model to study neurodegeneration or specifically Alzheimer's disease. Further, the instant specification does not disclose biological role of C1 protein of SEQ ID NO: 1, its relevance to any specific physiological process or clinical condition, and fails to provide

any scientific reasoning to support a statement that genes "participating in endoplasmic reticulum stress response" have a specific significance during neurodegeneration.

In the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. According to the specification of the instant application, "where the DNA encoding the protein of the present invention is abnormal or deficient, or where the expression level of the protein of the present invention is reduced, there occur a variety of diseases, for example, neurodegenerative diseases" (p. 30, lines 13-20 of the instant specification). The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or encoded protein is associated with any disease or disorder. To employ the DNA and the protein in the future methods of treatment by administration of pharmaceuticals comprising the claimed protein or DNA is not a "real world" because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the protein as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of the claimed peptide would prevent or treat a condition or disease, like Alzheimer's disease, Parkinson's disease, Down's syndrome, Huntington's disease or any other neurodegenerative disease (see p. 30), as implied by the specification. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible

"real world" use for the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 4-7 and 17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 17 is indefinite as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the elements that comprise the instant claimed kit. Claim 17, as presented, encompasses a kit for screening a compound or its salts that promotes or inhibits the activity of the protein [of SEQ ID NO: 1] and the only element that is recited in the

kit is the protein itself. Since the activity of the protein of SEQ ID NO: 1 is not known (see reasons of record in section pertained to the rejection under 35 U.S.C. 101 above), and because there appears to be no patentably significant utility in screening for compounds that affect the activity of the protein of SEQ ID NO: 1, one skilled in the art would now know as what material limitations define the claimed subject matter, a kit comprising protein of SEQ ID NO: 1.

(10) Response to Argument

1. Appellant traverses the rejection under 35 U.S.C. 101 of claims 1, 2, 4-7 and 17 at pp. 8-19 of the Appeal Brief. It is noted that while arguing that "there is sufficient evidence that the claimed protein has a well-established or specific, substantial, and credible utility for, *inter alia*, C1", p. 19 of the Brief, Appellant failed to articulate at least one specific, substantial, and credible utility for the claimed products within the entire text of the Brief.

At pp. 8-13 of the Brief, Appellant provides citations of case law pertaining to 35 U.S.C. 101, (*Diamond v. Chakrabarty, Brenner v. Manson, In re Fisher, In re Brana)*, refers to the PTO "Utility Examination Guidelines" and reviews the rejections of record during prosecution of the instant patent application. Appellant's review of the issue of utility, the case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress

for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

The instant claimed protein C1 of SEQ ID NO: 1 and its encoded DNA do not meet the requirements of 35 USC 101 as being useful because the instant specification fails to disclose even one specific and substantial credible utility for the claimed molecules. According to legal standard, a specification can meet the utility and enablement requirement for a new polypeptide or polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new molecules (an "evidence"), or a well-established utility for the claimed molecules would be *prima facie* obvious to the skilled artisan ("sound scientific reasoning"). Thus, the law requires that the patent application describes the utility of the claimed invention based on evidence or obviousness to one skilled in the art. The Examiner maintains that in the instant case, the asserted utility of the polypeptide of SEQ ID NO: 1 - to prevent and treat Alzheimer's disease (AD) and other neurodegenerative diseases - is not supported by any factual evidence or sound scientific reasoning at the time of filing. Specifically, there is no disclosure that the instant polypeptides or polynucleotides can be used as a marker for AD, or that the polypeptide of SEQ ID NO: 1 can be used for therapeutic purposes to treat AD. The result of experiments performed on cells with artificially altered genotype do not make it immediately obvious for one of skilled in the art that the instant C1 protein has a specific role in

etiology of AD. Thus, since the evidence of record is inadequate to support the asserted utility of the C1 protein, the instant invention clearly does not meet the requirement of 35 USC 101.

At pp. 13-14 of the Brief, Appellant summarizes that " [t]he Examiner erred in rejecting claims 1, 2, 4-7 and 17 on technical and legal grounds. Applicants have clearly established, on the record, the nexus between C1 protein (i.e., SEQ ID NO: 1) and enhanced expression in nerve cells subjected to endoplasmic reticulum (ER) stress. Applicants have further established, as the Examiner admits, that the expression of C 1 is enhanced in rat primary nerve cells that have been stimulated with J3 amyloid. See Office Action mailed June 10, 2009, pages 2-4. Applicants have clearly established that C 1 promotes cell death in SK-N-AS cells (human neuroblastoma) and that C 1 inhibits secretion of Aβ40 and Aβ42 in IMR-32 cells (human neuroblastoma). Office Action mailed June 10, 2009, pages 2-4. Indeed, the Office does not dispute Applicants' evidence of utility". Appellant's arguments have been fully considered but are not persuasive for the following reasons.

Example 4, p. 69 of the instant specification demonstrates that cells transfected with C1 gene had increased survival rate as compared to control cells (see Figures 1 and 2). The specification does not disclose any scientific reasoning as how these data explain a role of C1 protein in Alzheimer's disease, Down's syndrome, prion disease or any other neurodegenerative diseases. There is no reliance on prior art of record to support a conclusion that these results have a meaningful significance for those of skill in the art with respect to neurodegenerative process. Therefore, the results of Example 4 do not allow a conclusion that C1 protein is useful to prevent or treat AD.

Further, Example 5, p. 69 of the instant specification describes results of experiments in which cells transformed with C1 gene were recorded to secrete less Aβ than control cells. Appellant argues that "C1 inhibits secretion of Aβ40 and Aβ42"; however, the record shows that it is not the administration of C1 but the artificial overexpression of the C1 gene causes changes in secretion of amyloid. There is no evidence that the protein C1 itself inhibits any physiological function or process of secretion of Aβ. Moreover, there is no explanation given as how spontaneous secretion of Aβ in cells transfected with C1 relates to etiology of Alzheimer's disease in particular, even more for Parkinson's disease, in which amyloid pathology is not present, and to neurodegenerative diseases in general. The art does not recognize the *in vitro* model of an artificially transfected neuroblastoma cell line monitored for Aβ secretion as an art accepted model of neurodegeneration. Thus, the evidence of record does not support substantial and specific utility for the claimed molecules to treat and diagnose neurodegenerative diseases. These uses are not substantial because they represent merely hypothetical possibilities for which these molecules have not been used in the real world. They are also not specific utilities, because they do not credibly relate polypeptide of SEQ ID NO: 1 to any specific disease, including Alzheimer's disease.

§101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form, *Brenner*, 383, U.S. at 534-35, 148 USPQ at 695. *Brenner's* standard has been interpreted to mean that "vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" would not satisfy §101. See *Kirk*, 376 F. 2d at 945 153 USPQ at 55 (interpreting *Brenner*).

Therefore, Appellant's statement that "the office does not dispute Applicants' evidence of utility", p. 14 of the Brief, mischaracterizes the Examiner's position. The results of scientific experiments presented in the specification as filed are not doubted or disputed by the Examiner. However, the Examiner maintains that the evidence of record would not have suggested a specific biological function to support the use of C1 protein in therapeutic, prophylactic or diagnostic purposes with respect to any neurodegenerative disease or disorder, to a person skilled in the art at the time the application was filed. In the terms used by the *Brenner* Court, such a characterization does not provide a specific utility in currently available form.

Appellant argues at p. 14 of the Brief, that the Declaration of Tomomichi Watanabe of March 06, 2008 filed 37 C.F.R. § 1.132 provided additional highly statistically significant data however, "the Office acknowledges Applicants' evidence but accords it no weight", pp. 14-15 of the Brief. Appellant's argument has been fully considered but is not persuasive.

The Declaration of Tomomichi Watanabi under 37 CFR 1.132 filed on March 06, 2008 was fully considered and answered at p. 5 of the Paper mailed on May 07, 2008. Specifically, the Declaration is insufficient to overcome the rejection of claims 1, 2, 4-7 and 17 based upon 35 U.S.C. 101 because it is limited to presenting additional data obtained on cells transfected with C1 protein and studied for cell death promotion activity and secretion of Aβ. As an essential matter, the validity of the data is not and has never been disputed by the Examiner. However, the Declaration clearly states that the experiments were conducted under the same conditions as those in Example 4, p. 2 of the Declaration, and it fails to address the significance of the experimental model used by Appellant with respect to Alzheimer's disease, for example, or to provide any support or further explained the relevance of findings presented in the instant

specification to neurodegenerative pathology of the brain. The asserted utility as originally presented in the specification is to prevent and treat AD and other neurodegenerative diseases, p. 30 of the specification. However, the Declaration does not explain how the data presented in Example 4 and further additional data of the Declaration support this utility.

At p. 15 of the Brief, Appellant submits that "the utility of Applicants' claimed invention is also confirmed by prior art evidence" and refers to articles of Seubert et al., Siemers et al. and Fleisher et al. The Examiner disagrees. Article of Seubert et al., 1992 is cited by Appellant to point out "that the state of the art at the relevant time established a connection between Alzheimer's disease and Aβ". However, Appellant's asserted utility is to use the C1 protein of SEQ ID NO: 1 to treat Alzheimer's disease and other neurodegenerative diseases, p. 30 of the specification, and there is no evidence of record that the instant C1 protein is associated with Alzheimer's disease. Seubert et al. article does not teach that any protein that is artificially introduced into a transfected cell line and changes spontaneous Aβ release becomes immediately suitable as a useful therapeutic compound to prevent or treat Alzheimer's disease.

Further, Appellant's argument that compounds, such as LY450139, that decrease Aβ secretion and therefore have potential therapeutic significance in AD treatment (articles by Siemers et al. and Fleisher et al.), is not disputed. However, in the instant case, the evidence of record does not provide for C1 to be one of those compounds because there is no record of suppression of Aβ secretion upon administration of C1. One skilled in the art readily appreciates that the genetically altered cells are reasonably expected to express different types/amounts of proteins as compare to wild type cells. There is no explanation given in the specification or

presented by Appellant that would allow a conclusion that C1 overexpression is directly associated with the biological significance of C1 protein in Aβ secretion process.

At pp. 16-17 of the Brief, Appellant argues that the Examiner's reliance on *In re Fisher* "is misplaced and thus improper. In *Fisher*, the applicants argued that the claimed expressed sequence tags (ESTs) had utility as a nucleotide sequence alone, such as a research tool for monitoring gene expression [...]. In the present application, Applicants' teachings are not mere disclosure of a DNA fragment corresponding to a polynucleotide sequence to a putative polypeptide with no known function (as did Fisher's). The evidence of record provides detailed information about the claimed subject matter, such as full and novel C 1 polypeptides, full and novel DNAs, expression analysis, differential expression in specific tissues and cells, differential expression in specific tissues and cells under specific cellular conditions, highly specific relations between cell state and C 1, and inhibitory activity by C 1 against Aβ secretion". Appellant's arguments have been given careful consideration but it is not persuasive that *In re Fisher* situation is not applicable here.

The U.S. Court of Appeals for the Federal Circuit addressed the utility requirement in the context of a claim to DNA. *See In re Fisher,* 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the

'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.*

The court held that a specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage," (*Id.,* slip op. at 15), in the instant case Appellant's asserted utility for the polypeptide of SEQ ID NO: 1, particularly in view of a lack of knowledge as to the biological function of the polypeptide of SEQ ID NO: 1 or its relevance to Alzheimer's or any other neurodegenerative disease, constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use. Appellant argues that "the evidence of record provides detailed information about the claimed subject matter", p. 16 of the Brief, but the evidence presented is limited to disclosure of the structure of a polypeptide of SEQ ID NO: 1, its encoding DNA, and limited experimental results none of which support the asserted utility.

At p. 17 of the Brief, Appellant states that "the Office improperly relies on *In re Brana* to support its lack of utility rejection" and further explains the details of *Brana* case at pp. 17-18. Appellant's reliance on *In re Brana* appears to be misplaced because this case law was never cited or relied upon by the Office during prosecution of the instant patent application.

Characterization of the claimed nucleic acids of SEQ ID NO: 2 and encoded protein of SEQ ID NO: 1 as affecting secretion of Aβ or survival of cells artificially transfected with this nucleic acid is clearly not sufficient to establish their utility. The art does not recognize the cell model used in the experiments disclosed in the instant specification as acceptable for "Alzheimer's disease, Parkinson's disease and the like". The Examiner does not dispute the experimental data presented by Appellant; however, the issue at hand remains that in the absence of knowledge of the biological significance or activity of these particular claimed nucleic acids and polypeptide and their relevance to the process of cell death or secretion of abnormal amyloid protein, the instant C1 is suitable only for future research. Appellant states at pp. 18-19 of the Brief that, "[g]iven the nexus between C 1 protein and enhanced expression in nerve cells subjected to endoplasmic reticulum stress; enhanced expression of C 1 in nerve cells stimulated with J3 amyloid; C 1 promotion of cell death in human neuroblastoma; and C 1 inhibition of secretion of A1340 and A1342, one having ordinary skill in the art would appreciate a relationship between C 1 and Aβ secretion processes", but the record does not support Appellant's position. Provided that significance of the "endoplasmic reticulum stress" is not fully explained in etiology of neurodegeneration and that cells artificially transfected with a novel nucleic acid are not an art-recognized model for Alzheimer's pathology, the specification provides no meaningful explanation regarding relationship "between C 1 and Aβ secretion processes" for one of skill in the art. The specification provides no meaningful guidance regarding how to use such information in any practical way. The specification provides no guidance on how such information would allow those skilled in the art to use the claimed proteins and polynucleotides in a specific substantial way. Thus, Appellant claims products

asserted to be useful as therapeutics for future clinical applications but the specification does not disclose how to interpret those data and reasonably correlate the experimental results with the asserted use.

The Examiner maintains that since the instant specification does not disclose a specific substantial and credible "real world" use for the instant protein and its encoding DNA in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful. The instant rejection is maintained.

2. Claims 1, 2, 4-7 and 17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

3. At pp. 19-20 of the Brief, Appellant argues that "[t]he Office's rejection is premised on the allegation that the C 1 protein is not sufficiently characterized (citing to the reasoning in Section 5 of the pending Office Action), which according to the Examiner is contingent on the rejection under 35 U.S.C. § 101". Appellant's argument has been fully considered but is not persuasive because it fails to address the issue at hand and define the limitation "activity of the protein [C1]". The Examiner maintains that since the activity of the C1 protein is not known, one skilled in the art would now know as what material limitations define the claimed subject matter, a kit for screening a compound that promotes or inhibits the activity of the protein of SEQ ID NO: 1, and the rejection is maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Olga N. Chernyshev/

Primary Examiner, Art Unit 1649

Conferees:

/Jeffrey Stucker/

Supervisory Patent Examiner

Art Unit 1649

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646